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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,549	01/27/2005	Masayuki Miyasaka	1422-06569PUS1	8830

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,549	MIYASAKA ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim 4 is objected to because of the following informalities: it is not clear what is meant by the term "sideration". Appropriate correction is required.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means, that based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claim.

The claim encompasses an agent for treating or preventing a disease associated with biological events mediated by any L-selectin, P-selectin and chemokine.

(B) The level of predictability in the art.

There is no known correlation between mediation by L-selectin, P-selectin and chemokine and the treatment or prevention of any specific disease.

(C) The existence of working examples.

There are no examples in the specification of prevention or treatment of any specific disease.

(D) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The terminology "a disease associated with biological events mediated by any L-selectin, P-selectin and chemokine" encompasses such a large number of possible diseases that it would take an undue amount of experimentation to determine for the prevention or treatment of which specific disease the claimed agent would be useful.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

On page 3 of the specification it is stated that the object of the present invention is to provide an agent for treating or preventing a disease associated with biological events mediated by any L-selectin, P-selectin and chemokine, which can improve symptom of a disease such as inflammatory disease, allergic disease, cancer metastasis, myocardial disease and multiple organ failure, and can exhibit high affinity in a living body. The specification provides evidence that the claimed compounds are useful in binding L-selectin, P-selectin and chemokine. However, there is no known correlation between binding L-selectin, P-selectin or chemokine and the prevention or treatment of any specific disease. Applicant has not provided any evidence that the claimed compounds can be used in prevention or treatment of any specific disease. Applicant's statement on page 3 of the specification that the claimed compounds can be used in prevention and treatment of diseases is seen to be merely speculative and

would require additional experimentation to determine if the claimed compounds can be used in prevention or treatment of a specific disease.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawashima et al (The Journal of Biological Chemistry, Vol. 277, No. 15, pp. 12921-12930, (2002)).

Kawashima et al disclose the claimed oligosaccharides of chondroitin sulfate or dermatan sulfate (page 12921).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ferrari (U.S. Patent No. 5,705,493).

Ferrari discloses oligosaccharides made by hydrolysis of sulfated chondroitin sulphate and dermatan sulfate (column 2, lines 20-67). Even thought Ferrari does not specifically disclose the claimed tetrasaccharides or octasaccharides, said saccharides would have been inherently contained in the mixture of oligosaccharides disclosed by Ferrari.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bevilacqua et al (U.S. Patent No. 5,527,785) in view of Ferrari (U.S. Patent No. 5,705,493).

Bevilacqua et al disclose oligisaccharides which are useful in ameriolating P- and L-selectin disorders (column 6, lines 15-30). Bevilacqua et al disclose oligosaccharides having from about 2 to about 17 saccharide units and most preferably four to six units whic are fragments of heparin sulfate or other glycosaminoglycans (column 5, lines 24-65). Bevilacqua et al do not specifically disclose fragments of chondroitin sulfate or dermatan sulfate. However, since glycosaminoglycans, such as chondroitin sulfate and dermatan sulfate, were well known in the art at the time the claimed invention was made

as disclosed by Ferrari, a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to use fragments of chondroitin sulfate or dermatan sulfate as other glycosaminoglycans disclosed by Bevilacqua et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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